

## REMARKS

The Official Action of 30 November 2006 has been carefully considered and reconsideration of the application as amended is respectfully requested.

The claims have been amended to recite that the respective components are present in respective amounts effective to provide the formulation with synergistic anti-dermatophytic activity. Since the original claims recite the synergistic activity the amendment does not narrow the scope of the claims. The synergistic activity of the claimed components is described in the specification as filed at, for example, page 1, first paragraph, and page 4, fifth paragraph, and is exemplified in the Examples beginning on page 7 of the specification. Withdrawn claims 14-26 have been amended to depend from the elected product claims to facilitate their rejoinder upon the allowance of the elected product claims (see MPEP 821.04). New claims 27-28 have been added to cover subject matter deleted from original claims 1 and 15.

The claims stand rejected under 35 USC 103(a) as allegedly being unpatentable over Baroni et al in view of Bhagwat et al, Vandenberg et al and Friedman et al. Applicants respectfully traverse these rejections.

The claimed invention provides a novel **synergistic** antifungal formulation active against dermatophytic fungi comprising a garlic extract in propylene glycol and an essential oil of *Mentha specata* var Ganga or cinnamon oil, optionally in

combination with menthyl acetate or geraniol. In addition to discovering the synergistic activity of the claimed combination of components, Applicants found, surprisingly, that the oil of *Mentha specata* var Ganga acts as a preservative for the formulation. The shelf life of the claimed formulation is more than one year.

The Examples in the present specification show the surprising anti-dermatophytic fungal activity of the claimed combination of components. In particular, the Examples show that the claimed oils, *Mentha specata* var Ganga and cinnamon oil, produce a synergistic anti-dermatophytic fungal effect when used together or separately with garlic extract. These results could not have been expected from the prior art since, as shown in Example 1 beginning on page 7 of the specification, other essential oils such as *Eucalyptus* hybrid and *Mentha citrata*, produced **antagonistic** effects against *Candida albicans* and *Trichophyton rubrum* when combined with garlic extract. Other combinations produce only an indifferent or additive (as opposed to a synergistic) effect (see Table 2 on pages 9-10).

The Examples in the specification provide evidence of the synergistic effects of the claimed combination of components in the recited amounts that is sufficient to rebut any alleged case of *prima facie* obviousness set forth by the cited art. Indeed, as discussed next, there is nothing in any of the cited references that would show or suggest the surprising anti-dermatophytic activity of the claimed combination of components in the recited amounts whereby such activity must be considered to be **unexpected**.

Baroni et al in paragraphs 0081 and 0104 list a number of antimicrobial essential oils, actives of essential oils and a number of solvents which are not limited to cinnamon oil or garlic extract or propylene glycol. Baroni et al also mention eucalyptus oil in paragraph 0081. In contrast to the claimed invention (Example 1; pg 7) essential oil of *Eucalyptus* hybrid (*E. citriodora*), *Mentha citrate* etc. produced antagonistic effects in use against *Candida albicans* and *Trichophyton rubrum* when evaluated with garlic extract. Thus it could not have been expected which, if any, of the antimicrobial essential oils and actives of essential oils listed by Baroni et al would produce synergistic effects when used in suitable amounts with garlic extract.

In the claimed invention, selected oils, i.e., *Mentha specata* var Ganga Cinnamon oil produce a synergistic effect when used together or separately with garlic extract in the recited amounts. Baroni et al further disclose (paragraph 0085) that combining antimicrobial essential oil or actives or their mixture with peroxygen bleach delivers excellent disinfecting properties. In the claimed invention no peroxygen bleach is necessary.

Bhagwat discloses compositions containing antimicrobials and urea for the treatment of dermatological disorders. In Col 8, Table 2, Bhagwat et al disclose a formulation of a lotion composed of a number of ingredients. This formulation is not limited to cetyl alcohol, steryl alcohol and propylene glycol. Bhagwat does not show or suggest the synergistic effects of the claimed formulation.

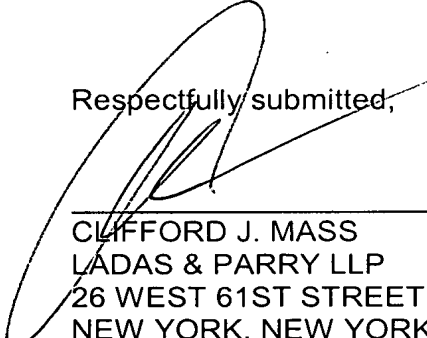
Vanderbergh et al in Col 6, Table 2, teach 1% garlic extract produces highest concentration of Fungal Inhibitory Compounds. In the claimed invention garlic extract may be used at a concentration of 1 to 2.5% (see claim 5). Example 1 of the present specification teaches that the combinations of essential oils and garlic extract should be made according to their minimum inhibitory concentration (MIC's). The resultant synergistic activity of the claimed combinations is not shown or suggested by Vandenberg.

Friedman et al teach an anti-fungal composition consisting of an extract of botanical materials and an essential oil. Friedman et al have listed a number of essential oils in Col 2 lines 3-49 and is not limited to cinnamon oil. The concentration of essential oils used by Friedman et al is 0.1 to 5%. In the claimed invention, *Mentha specata* var Ganga or Cinnamon oil alone or in combination are used as essential oils. Neither Friedman et al nor Vandenberg et al have used *Mentha specata* var Ganga as an essential oil. Even if these two citations are combined they fail to teach the claimed formulation or the surprising anti-dermatophytic fungal properties thereof.

In short, none of the cited references, either alone or in combination, show or suggest the novel synergistic antifungal properties of the claimed formulation. Accordingly, the presence of such properties is respectfully considered to be unexpected and probative of nonobviousness.

In view of the above, Applicants respectfully submit that the prior art rejection of record has been successfully traversed and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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